

**REMARKS**

Upon entry of the present amendment, claims 16, 19, 20 and 26 will be amended, and claims 27-29 will be added whereby claims 16, 19, 20 and 25-29 will be pending.

By the amendment herein, claim 16 has been amended to recite “A whitening external preparation composition for skin” and *Glycyrrhiza glabra* extract or lily extract in portion (B) of the claim. Moreover, similar changes have been made to dependent claims 19 and 20. Additionally, new claims 27-35 have been added.

Support for the amendments appears in Applicants originally filed application including the originally filed claims and Applicants’ specification at page 9, line 28, page 21, line 34 and page 15, line 27 *inter alia*. For example, Applicants’ specification at page 9, line 28, supports “the amount of (A) ingredient is from 0.00001 to 5 % by mass”; Applicants’ specification at page 21, line 34, and page 15, line 27, supports “the amount of (B) ingredient is from 0.00001 to 10 % by mass” (because *Glycyrrhiza glabra* extract belongs to (C2) (as seen at the second paragraph on page 20; and lily extract belongs to (C1) (as seen at the first full paragraph on page 12); the description, page 21, line 34, supports “the amount of (B) ingredient as cactus extract is from 0.00001 to 10 % by mass” (because cactus extract belongs to (C2) (as seen at the second paragraph on page 20); and the description, page 16, line 16, supports “the amount of (B) ingredient as Panax ginseng extract is from 0.00001 to 5 % by mass” (because Panax ginseng extract belongs to (F1) (as seen at the paragraph bridging between pages 13 and 14). Accordingly, no new matter should be present in the amendment.

Reconsideration of the restriction requirement, the objection and the rejection of record, and allowance of the application in view of the following remarks are respectfully requested.

**Discussion Of Telephone Interview**

Applicants hereby express appreciation for the courtesies extended by Examiner Susan Coe Hoffman during a December 18, 2008 telephone interview with Applicants' representative Arnold Turk.

During the telephone interview, Applicants' representative inquired from the Examiner the type of showing that the Examiner would find persuasive for establishing unexpected results. The Examiner indicated that the claims do not recite amounts of ingredients therein and are not limited to ingredient (A) with the elected *Glycyrrhiza glabra* extract. The Examiner indicated that the results must be commensurate in scope with the claimed subject matter and be statistically significant.

Regarding whether tests present quantifiable data, Applicants representative noted that he was advised that "Melanin Production Suppression" is a standard test with the whiteness levels being readily ascertainable, and indicated that a photograph could be forwarded illustrating the results of such test.

The correction of the spelling of *Cistus monoperiensis* to *Cistus monspeliensis* was discussed with the Examiner suggesting that evidence in the form of a Declaration be presented that *Cistus monspeliensis* was intended in the originally filed application.

**Response to Restriction Requirement**

The restriction requirement has been maintained and made Final with claims 16, 19, 20, 25 and 26 being examined on the merits only with respect to the elected species *Glycyrrhiza glabra* extract.

Applicants are permitting the non-elected subject matter to remain pending subject to rejoinder upon allowance of the elected subject matter.

### **Response to Objection to Specification**

The amendment filed June 30, 2008 is objected to under 35 U.S.C. 132(a) because it is asserted that the amendment introduces new matter into the disclosure.

The objection contends that the added material which is not supported by the original disclosure is the amendment to change *Cistus monoperiensis* to *Cistus monspeliensis*. The objection contends that there is no evidence to support Applicants' assertion that these are the same plants.

In response, Applicants submit that the objection does not address the evidence submitted with Applicants' response filed June 30, 2008, which noted that the specification and claims have been amended to include the more conventional spelling of *Cistus monspeliensis* L. In this regard, Applicants noted that U.S. Patent No. 6,313,214 to Tamai, which is utilized in the rejection of Applicants' claims, discloses the same "*Cistus monoperiensis* L." as recited by Applicants, referencing, for example, Tamai, column 2, lines 44; and column 3, line 60. It is noted that the more conventional academic spelling is *Cistus monspeliensis* L. and the specification and claims have been amended to include this academic spelling. Reference was made, for example, to <http://commons.wikimedia.org/wiki/Cistus> and [http://commons.wikimedia.org/wiki/Cistus\\_monspeliensis](http://commons.wikimedia.org/wiki/Cistus_monspeliensis), and downloads from these websites dated June 29, 2008 were submitted with the response.

Accordingly, for at least these reasons, the objection should be withdrawn.

Moreover, to advance prosecution and in accordance with the suggestion by the Examiner during the above-noted interview, Applicants are submitting herewith a Declaration signed by one of the inventors, i.e., Taku Hoshino, stating that a misspelling of the academic name of “Cistus monspeliensis L.” is being corrected.

According this ground of objection should be withdrawn.

### **Response to Rejection under 35 USC 112, First Paragraph**

Claims 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The rejection contends that claims 19 and 20 have been amended to change Cistus monoperiensis to Cistus monspeliensis, and that there is no evidence to support Applicant’s assertion that these are the same plants.

In response to this ground of rejection, Applicants refer the Examiner to the above-note Declaration of Taku Hoshino, and request that this ground of rejection be withdrawn.

### **Rejection Under 35 U.S.C. 103(a)**

Claims 16, 19, 20, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamai (US 6,313,214) and Hadas (IJS 5,609,875) for the reasons set forth in the previous Office action.

The rejection indicates that all of applicant’s arguments regarding this ground of rejection have been fully considered but are not persuasive as the results are not considered to support a claim for unexpected results. The rejection contends that the data presented in Table 1 appear to be qualitative judgments rather than quantifiable data and not statistically significant. The rejection further contends that without being able to separately evaluate the effectiveness of G.

glabra, it cannot be determined if the results shown in Table 1 are actually synergistic rather than additive.

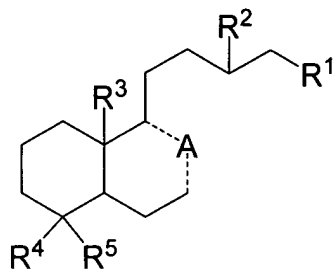
As previously noted by Applicants, the rejection asserts that Tamai teaches the compounds claimed as ingredient (A), formula 1, and that these compounds can be extracted from the plants claimed in claims 19 and 20. The rejection contends that Tamai teaches that these compounds are used to treat skin ageing by lightening the skin, but that Tamai does not teach using Glycyrrhiza glabra extract in the composition.

The rejection asserts that Hadas teaches using Glycyrrhiza glabra extract for lightening the skin.

The rejection concludes that, "It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose."

The rejection further points to data at pages 62 and 63 (apparently pages 65 and 66) of Applicants' specification and notes that the specification states that this data shows synergistic results for the combination of ingredient (a) and G. Glabra extract. However, the rejection contends that these results are not considered to show synergistic results. The rejection contends that the results in Table 2-1 appear to be qualitative judgments rather than quantifiable data, and that the burden is on the Applicants to show how offered data is of statistical significance.

In response to this ground of rejection, Applicants submit that one having ordinary skill in the art would not have arrived at a whitening external preparation composition for skin, as recited in Applicants' independent claim 16, by combining (A) one, or two or more compounds represented by formula (1) below:



in formula (1), R<sup>1</sup> represents -CH<sub>2</sub>OH or COOR<sup>6</sup>, R<sup>6</sup> represents hydrogen, a lower alkyl group having the number of carbon atoms of 1 to 3, or a cation capable of forming a salt with COO<sup>-</sup>, each of R<sup>2</sup> to R<sup>5</sup> independently represents a hydrogen atom or methyl group, and ···A··· represents =C(CH<sub>3</sub>)-, -C(CH<sub>3</sub>)=, -C(=CH<sub>2</sub>)-, -CH(CH<sub>3</sub>)- or -C(OH)(CH<sub>3</sub>)-; and

(B) *Glycyrrhiza glabra* extract or lily extract.

Moreover, Applicants submit that the compositions recited by Applicants comprising the recited ingredients (A) and (B) exhibit superior effects beyond the expectation of those skilled in the art at the time the invention was made.

Experimental tests shown below were carried out on behalf of the Applicants to clarify the superior effects of the compositions as recited by Applicants. In this regard, Applicants submit herewith a Declaration Under 37 C.F.R. 1.132 of Chiharu Koide. The Examiner is requested to review the showings regarding quantifiable data, such as at pages 12 and 13, and the examples and tables set forth in the Declaration with respect to unexpected showings associated with Applicants' claimed subject matter.

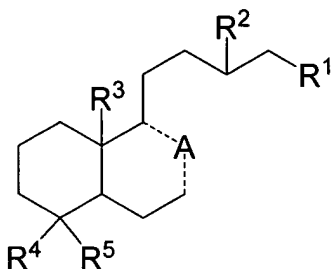
Thus, if for the sake of argument a *prima facie* case of obviousness is present, Applicants' showing of unexpected results establishes patentability of Applicants' claims subject matter. Accordingly, the rejection of record should be withdrawn.

Accordingly, Applicants submit that Applicants' compositions recited in claims 16, 19 and 20, and methods recited in claims 25 and 26 are patentable over the prior art of record, and the rejection should be withdrawn.

Still further, newly-added claims 27-35 are also patentable over the prior art of record because the prior art of record does not teach or suggest the claimed subject matter. Moreover, the Declaration also should be considered to establish unexpected results for the subject matter of these claims.

Thus, independent claim 27 is directed to an anti-aging external preparation composition for skin, comprising:

(A) one, or two or more compounds represented by formula (1) below:



in formula (1),  $R^1$  represents  $-\text{CH}_2\text{OH}$  or  $\text{COOR}^6$ ,  $R^6$  represents hydrogen, a lower alkyl group having the number of carbon atoms of 1 to 3, or a cation capable of forming a salt with  $\text{COO}^-$ , each of  $R^2$  to  $R^5$  independently represents a hydrogen atom or methyl group, and  $\cdots\text{A}\cdots$  represents  $=\text{C}(\text{CH}_3)-$ ,  $-\text{C}(\text{CH}_3)=$ ,  $-\text{C}(\text{=CH}_2)-$ ,  $-\text{CH}(\text{CH}_3)-$  or  $-\text{C}(\text{OH})(\text{CH}_3)-$ ; and

(B) cactus extract or Panax ginseng extract.

Claim 28 further patentably defines the subject matter of claim 27 by reciting that the compound represented by formula (1) is a compound, or a compound prepared from said compound extracted from one, or two or more plants selected from *Cistus ladaniferus* L., *Cistus creticus* L., *Cistus monspeliensis* L. and *Cistus salvifolius*.

Claim 29 further patentably defines the subject matter of claim 27 by reciting the anti-aging external preparation composition for skin as claimed in Claim 27, formed from one, or two or more extracts, containing said compound represented by formula (1), selected from *Cistus ladaniferus* L. , *Cistus creticus* L., *Cistus monspeliensis* L. and *Cistus salvifolius*.

Claim 30 further patentably defines the subject matter of claim 16 by reciting that the *Glycyrrhiza glabra* extract or lily extract is *Glycyrrhiza glabra* extract.

Claim 31 further patentably defines the subject matter of claim 16 by reciting that the *Glycyrrhiza glabra* extract or lily extract is lily extract.

Claim 32 further patentably defines the subject matter of claim 16 by reciting that the amount of (A) ingredient is from 0.00001 to 5% by mass; and the amount of (B) ingredient is from 0.00001 to 10% by mass.

Claim 33 further patentably defines the subject matter of claim 27 by reciting that the cactus extract or Panax ginseng extract is cactus extract.

Claim 34 further patentably defines the subject matter of claim 27 by reciting that the cactus extract or Panax ginseng extract is Panax ginseng extract.

Claim 35 further patentably defines the subject matter of claim 27 by reciting that the amount of (A) ingredient is from 0.00001 to 5% by mass; and the amount of (B) ingredient as cactus extract is from 0.00001 to 10% by mass or the amount of (B) ingredient as Panax ginseng extract is from 0.00001 to 5% by mass.

Accordingly, the rejection of record should be withdrawn, and the claims indicated to be allowable over the prior art of record.



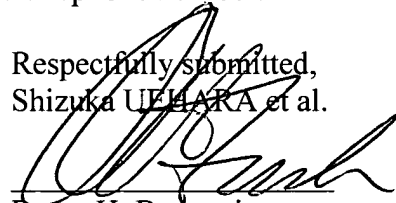
**CONCLUSION**

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the restriction requirement, objection and rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
Shizuka UELARA et al.



Bruce H. Bernstein  
Reg. No. 29,027

**Arnold Turk**  
**Reg. No. 33094**

March 9, 2009  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191